

Legal Division

GOVERNMENT EXHIBIT

Mark J. Haberberger Abbott Laboratories Dept. 322, Bldg. AP6D 100 Abbott Park Road Abbott Park, Illinois 60064-3500

Telephone: (708) 937-1788 Facsimile: (708) 938-1206

### By Federal Express

September 26, 1995

Glenn M. Engelmann General Counsel Zeneca Pharmaceuticals 1800 Concord Pike Wilmington, Delaware 19850



RE: <u>Illegal and/or Fraudulent Zeneca Marketing Activities</u>

### Dear Mr. Engelmann:

As counsel for TAP Pharmaceuticals Inc. ("TAP"), I am writing you concerning certain marketing activities being conducted by Zeneca Pharmaceuticals ("Zeneca") sales representatives that we believe are illegal and/or fraudulent. We are extremely concerned about this pattern of improper marketing activities by Zeneca, and we hereby demand that Zeneca immediately cease and desist from such activities, which are described below. We further demand that Zeneca provide us with its written assurance that such activities will not be repeated and that appropriate corrective measures will be taken.

We are especially concerned about Zeneca's offering free goods to customers as an inducement to purchase Zoladex, in violation of Medicare fraud and abuse laws. In a written proposal for Zoladex Depots submitted by Zeneca Sales representative Randy Payne dated July 17, 1995, a copy of which is attached hereto as Exhibit A, it is stated: "AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over \$11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX." The offering of free product conditional on the purchase of other products is clearly an improper inducement.

In addition, Zeneca sales representatives have also disseminated to customers various sales promotional materials that fraudulently misrepresent the difference in the anticipated return to the physician customer's practice from prescribing Zoladex instead of TAP's product, Lupron Depot. These Zeneca sales materials give cost information for Zoladex using the highest available volume price discount while the

Glenn M. Engelmann September 25, 1995 Page 2

comparable information shown for Lupron Depot does <u>not</u> accurately reflect the volume price discount that would be available.

For example, a letter from Zeneca Sales Representative Michele Willingham dated April 21, 1995, a copy of which is attached hereto as Exhibit B, is one of numerous recent Zeneca sales aids comparing a 72 vial discounted purchase of Zoladex to a 101 vial purchase of Lupron Depot using outdated TAP quantity discount information. The discounted price indicated for Lupron is \$344.00 while the actual published discounted price in effect for the relevant volume as of the date of the letter was \$339.98. The resulting comparisons of the anticipated return to practice in this letter are also erroneous.

Yet another type of improper activity Zeneca sales representatives have engaged in is the offering for sale of Zoladex at prices which appear to violate federal price discrimination laws. An example of this is the Zeneca sales aid attached hereto as Exhibit C. This aid shows a Zoladex price of \$229.47 for 25 and 50 units, which is below the published quantity discount prices of \$252.42 and \$243.81, respectively.

Finally, Zeneca sales representatives have engaged in another type of illegal activity by promoting products that have not yet received FDA approval. For example, the Zeneca proposal to a urology practice, attached hereto as Exhibit D, which was submitted by Zeneca sales representatives Chawn Tipton, Glenna Spell, and Gregg Agoston, promotes two products, Casodex and 3-month depot Zoladex, that have not yet received FDA approval.

We request a response to this letter by October 9, 1995.

Very truly yours,

Mark J. Haberberger Senior Attorney

Encl.

cc: Yasu Hasegawa (all w/encl.)

Dean Sundberg Jim Salanty

### EXHIBIT A

PROPOSAL FOR ZOLADEX DEPOTS

DR. RIVES DR. OYER

JULY 17, 1995

### NEW LOWER CASE QUANTITY DISCOUNT ZOLADEX PRICING

UNITS	AWP	COST	DISCOUNT	LESS
1-5)	<b>\$358.55</b>	\$286.84	0% * *	2% \$281.10
6 - 11	\$358.55	\$269.63	6%	\$264.24
12 - 23	<b>\$35</b> 8.55	\$261.02	9%	\$255.80
24-47	\$358.55	\$252.42	12%	\$247.37
48 - 59	\$358.55	\$243.81	15%	\$238.93
60 - 71	\$358.55	\$235.21	18%	\$230.50
72+	\$358.55	\$229.47	20%	\$224.88

### **LUPRON PRICING**

•			
UNITS	AWP	COST	DISCOUNT
1-11	\$477.50	\$382.00	0%
12 - 23	\$477.50	\$370.50	3%
24 - 47	\$477.50	\$363.00	5%
48 - 59	\$477.50	\$355.26	7%
60 - 71	\$477.50	\$347.62	9%
72 - 100	\$477.50	\$343,80	10%
101+	\$477.50	\$339.98	11%

ZOLADEX OFFERS THE SAME RESULTS AT A LOWER COST

<sup>\*\*</sup> DEEPEST DISCOUNT BEGINS WITH 72 ZOLADEX DEPOTS VS. 101 LUPRON DEPOTS

### DRS. RIVES & OYER CURRENTLY USES 50 DEPOTS PER MONTH

### **INVENTORY COMPARISON**

	ZOLADEX	LUPRON
COST	\$238.93 ( W/2% Discount )	<b>\$</b> 355.26
	<u>x 50</u>	<u>x 50</u>
COST PER MONTH	\$11,946.50	\$17,763.00
SAVINGS PER MONTH	\$5,816.50	•
SAVINGS PER YEAR	\$69,798.00	

### MEDICARE COMPARISON

	ZOLADEX	LUPRON
COST	\$358.55	<b>\$477.50</b>
	<u>x 50</u>	<u>x 50</u>
COST PER MONTH	\$17,927.50	\$23,875.00
SAVINGS PER MONTH	<b>\$5,947.5</b> 0	
SAVINGS PER YEAR	\$71,370.00	, ,
	•	•

<sup>\*\*</sup> REDUCED COST MEANS LESS CO-PAY FOR YOUR PATIENTS

### ZENECA AND ZOLADEX OFFER:

- \*\* SAME RESULTS AT A LOWER COST
- \*\* TIME SAVINGS AS ZOLADEX REQUIRES NO MIXING
- \*\* PAYMENT TERMS OF 2% 30 / NET 90 DAYS
- \*\* INVENTORY SAVING'S PER YEAR OF \$69,798.00
- \*\* MEDICARE SAVINGS PER YEAR OF \$71,370.00
- \*\* REDUCED CO-PAY COSTS FOR YOUR PATIENTS
- \*\* PATIENT EDUCATION ITEMS
- \*\* PHYSICIAN AND NURSING SUPPORT MATERIAL

AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over \$11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX.

WE WILL ALSO SPONSOR FREE TO YOUR PRACTICE, A ZENECA BUSINESS BUREAU WORKSHOP.

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT YOUR ZENECA PHARMACEUTICALS REPRESENTATIVE, RANDY PAYNE AT: 800-822-9209 ext. 6323.

TO PLACE AN ORDER: (VISA AND MASTERCARD ACCEPTED)

800-400-4140 Press 1

or to Fax an order: 800-289-9285

or contact Randy Payne at: 800-822-8209 ext. 6323

### **ZENECA BUSINESS BUREAU TOPICS**

- \*\* CODING SEMINARS (McVAY & ASSOCIATES)
- \*\* DIFFERENTIATING PRACTICE AND NEGOTIATING IN TODAY'S MARKET
- \*\* UROLOGY PRACTICE GUIDELINES AND HOW TO MAKE THEM WORK
- \*\* PERSONAL AND BUSINESS CHANGE MANAGEMENT AND RELATED ISSUES
- \*\* HEALTH REFORM AND NEW SYSTEMS FOR HEALTH CARE DELIVERY
- \*\* POSITIONING AND MARKETING OF UROLOGICAL PRACTICES
- \*\* OUTCOME MANAGEMENT
- \*\* CAPITATION
- \*\* SETTING UP A CAPITATED UROLOGY PRACTICE

EXHIBIT B

ZENECA
Pharmaceuticals
A Business Unit of Zeneca Inc

SPECIALTY C

Michele Willingham Specialty Sales Represent

Voice Mail (800) 822-9209.

PO Box 692 Okemos

Michigan 48805-0692



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April 21, 1995 Jennifer McConkie 211 S. Crapo Mt. Pleasant, Michigan 48858

Dear Jennifer,

Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has <u>new</u> volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.

Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice \$57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%.

Zoladex comes pre-packaged and does not require any mixing before injection. Zoladex can now be paid for with Visa or MasterCard.

Sincerely.

Michele Willingham

Zeneca Specialty Care Representative

#### **ZOLADEX and LUPRON QUANITY DISCOUNT COMPARISONS**

#### **ZOLADEX**

**Direct Pricing** 

Medicare AWP

\$\$Return / % Return

72+ \$224.88

\$358.55

**\$133.67** 59%

 $72 \times $224.88 = $16,191.36$ 

 $72 \times $358.55 = $25,815.60$ 

\$9,624.24 59%

based on your use of 480 depots annually, with our 2% discount these are the comparisons

\$107,942.40

\$172,104.00

\$ 64,161.60 59%

2% /30 Net 90

#### LUPRON

**Direct Pricing** 

Medicare AWP

\$\$Return / % Return

101+ \$344.00

\$477.50

\$133.50

39%

 $101 \times $334.00 = $34,744.00 \quad 101 \times $477.50 = $48,227.50$ 

\$13,483.05

39%

based on your use of 480 depots annually, these are the comparisons

\$165,120.00

\$ 229,200.00

\$ 64,080.00

30%

Based on the above comparison, Zoladex will save your practice the following:

An annual cash savings of \$57,177.60

A 59% return on Investment vs. Lupron's 39%

An opportunity to control inventory by ordering 72 Zoladex rather than 101 Lupron

An increased cash flow

### EXHIBIT C

(LESS 2%) PROFIT PER ORDER OF 18 PROFIT WITH 2% DISCOUNT PROFIT PER YEAR @ 216 UNITS	\$2323.4* \$2406.06 \$28,872,72	\$1926.00 \$1926.00 \$23,112.00	\$29,704.32
PROFIT ADVANTAGE WITH ZOLA PROFIT ADVANTAGE PER YEAR	DEX PER MONTH:	\$480.06 \$5,760.72	-\$831.60

### 2. ASSOCIATES IN UROLOGY: 50 UNITS

	ZOLADEX	LUPRON	LUPRON
COST PER UNIT @ 50 DISCOUNT RECEIVED TOTAL INVOICE CHARGE COST PER YEAR @ 600 UNITS	\$229.47 (20%) \$11,473:50 \$137,682.00	\$355.50 (7%) \$17,775,00 \$213,300.00	(MAX, 101) \$339.98 (11%) \$34,337.98 \$203,988.00
SAVINGS PER MONTH WITH ZOL SAVINGS PER YEAR WITH ZOL	LADEX: \$6,301.50 ADEX:	\$75,618.00	\$66,306.00
PROFIT PER UNIT @ 50 PROFIT IF PAY IN 30 DAYS	\$129.08 \$133.67	\$122.00 \$122.00	\$137.52 \$137.52
PROFIT PER ORDER OF 50 PROFIT WITH 2% DISCOUNT PROFIT PER YEAR @ 600 UNITS	\$6454.00 \$6,683.50 \$80,202.00	\$6100.00 \$610 <u>0.00</u> \$73,200.00	\$82,512.00
PROFIT ADVANTAGE WITH ZOL PROFIT ADVANTAGE PER YEA	ADEX PER MONTI	1: \$583.50	-\$2,310.00

### 3. LONG BEACH UROLOGY ASSOCIATES: 55 UNITS

entaŭ e	ZOLADEX	LUPRON	LUPRON (MAX. 101)
COST PER UNIT @ 55 DISCOUNT RECEIVED TOTAL INVOICE CHARGE COST PER YEAR @ 660 UNITS	\$229.47	\$355.50	\$339.98
	(20%)	(7%)	(11%)
	\$12,620.85	\$19,552.50	\$34,337.98
	\$151,450.20	\$234,630.00	\$224,386.80
SAVINGS PER MONTH WITH ZOI SAVINGS PER YEAR WITH ZOI	DLADEX: \$6,931.65 LADEX:	\$83,179.80	\$72,936.60
PROFIT PER UNIT @ 55 PROFIT IF PAY IN 30 DAYS	\$129.08	\$122.00	\$137.52
	\$133.67	\$122.00	\$137.52

P.06

PROFIT WITH 2% DISCOUNT PROFIT PER YEAR @ 660 UNITS		\$6710.00 \$80,520.00 I: \$641.85	\$90,763.20
	• • -	• •	
PROFIT ADVANTAGE WITH ZOL	• • -	• •	-\$2,541.00

### 4. COAST UROLOGICAL MEDICAL GROUP: 25 PER MONTH

	ZOLADEX	LUPRON	LUPRON (MAX. 101)
COST PER UNIT @ 25	\$229.47	\$363,00	\$339.9B
DISCOUNT RECEIVED	(20%)	(5%)	(11%)
TOTAL INVOICE CHARGE	\$5736.75	\$9075.00	<b>\$34,</b> 337.98
COST PER YEAR @ 300 UNITS	\$68,841.00	\$108,900.00	\$101,994.00
SAVINGS PER MONTH WITH ZO	LADEX: \$3,338.25	•	
SAVINGS PER YEAR WITH ZOLA	ADEX:	\$40,059.00	\$33,153.00
PROFIT PER UNIT @ 25	\$129.08	\$111.18	\$137.52
PROFIT IF PAY IN 30 DAYS (LESS 2%)	\$133.67	\$111.18	\$137.52
PROFIT PER ORDER OF 25	\$3227,00	\$2779.50	
PROFIT WITH 2% DISCOUNT	\$3341.75	\$2779.50	
PROFIT PER YEAR @ 300 UNITS	\$40,101.00	\$33,354.00	\$41,256.00
PROFIT ADVANTAGE WITH ZOL	ADEX PER MONTH	<b>\$562.25</b>	
PROFIT ADVANTAGE PER YEAL		\$6,747.00	-\$1,155.00

### **SUMMARY**

TOTAL GROUP SAVINGS PER YEAR: \$201,903.28

TOTAL GROUP PROFIT ADVANTAGE PER YEAR: \$27,211.92



# Analysis and Proposal to Urologic Services Inc.

Submitted by:
Chawn Tipton
Glenna Spell
Gregg Agoston
Zeneca Pharmaceuticals



Zeneca Pharmaceuticals is dedicated to improving current options for treating the patient with prostate cancer. Currently we supply Zoladex 3.6 mg (Goserelin Acetate) and Metastron (Strontium 89). In 1995 we will launch Casodex an anti-active and in 1996 Zoladex 3 month depot.

Studies documented that Zoladex is equal in efficacy to Orchiectomy for prostate cancer patients (European Zoladex Study). New data proves that Zoladex used in combination with Flutamide can extend survival for prostate cancer patients when compared to Orchiectomy alone(Denis,1993)<sup>1</sup>.

The following proposal outlines our new quantity discount program for Zoladex. It also gives reasons why Signature Urologic Services Inc. should switch patients to Zoladex.

<sup>&</sup>lt;sup>1</sup> See accompanying full prescribing information.

### CURRENT ANALYSIS:

## NEW ZOLADEX PRICING STRUCTURE EFFECTIVE 3-23-95

UNITS	AWP Medicare Allowable	COST	DISC	LESS . 2%*	PROFIT / with 2% disc.
1-5	\$358.55	\$286.84	0%	\$281.10	\$77.45
6-11	\$358.55	\$269.63	6%	\$264.24	\$94.31
12-23	\$358.55	\$261.02	9%	\$255.80	\$102.65
24-47	\$358.55	\$252.42	12%	\$247.37	\$111.18
48-59	\$358.55	\$243.81	15%	\$238.93	\$119.62
60-71	\$358.55	\$235.21	18%	\$230.50	\$128.05
72+	\$358.55	\$229.47	20%	\$224.88	\$133.67

\*2% Discount for payment in 30 days

### CURRENT LUPRON PUBLISHED PRICING STRUCTURE

UNITS	AWP Medicare Allowable	COST	DISC	PROFIT
1-11	\$477.50	\$382.00	0%	\$95.50
12-23	\$477.50	\$370.50	3%	\$107.00
24-47	\$477.50	\$363.00	5%	\$114.50
48-100	\$477.50	\$355.50	7%	\$122.00
101+	\$477.50	344.00	10%	\$133.50

# FINANCIAL ANALYSIS: UROLOGIC SERVICES INC.

	Reimbursement		Zoladex	Lupron
1	Reminute	Medicare	\$286.84	\$382.00
2		Patient / co-pay	\$71.71	\$95.50
3		Total	<u>\$358.55</u>	<u>\$477.50</u>
4	Direct cost		\$229.47 72+	* \$324.53 101+ *approx. cost
5	Less 2% disc. for payment net 30.		\$224.88	N/A ··
6	State & local Tax 6%		\$13.49	\$19.47
7	Total Cost		\$238.37 (5+6)	\$344.00 (4+6)
8	Gross Profit/inj. (3-7)		\$120.18	\$133,50

Combined usage of Zoladex and Lupron for 1994 was 3300 depots/kits. The following shows how Zoladex can improve operations based on 3300 depots used in 1995.

Based on 3300 depots/kits	Zoladex	Lupron	Difference
Patient out of pocket/co-ins. #2x3300	\$236,643	\$315,150	<u>\$78.507</u>
State tax liability #6x3300	\$44,517	\$64,251	\$19,734
Cost of drug	\$742,104 #5x3300	\$1,070,949 #4x3300	\$328,845
State Tax liability + Cost of drug #6x3300	\$786,621	\$1,135,200	<b>\$</b> 348,579

This analysis shows that Zoladex will save your patients/co-insurance \$78,507.

Zoladex will improve cost effectiveness of by \$348,579. Zoladex helps position Urologic Services Inc., for managed care and capitation.

### OTHER CONSIDERATIONS:

\*Robert Eidus M.D., Choice Care Vice President and Chief Medical Officer, stated in the April General Surgery edition of Medical Economics, that Choice Care has "'900 primary care physicians and 2,400 specialists." 'It's nice to have a large panel, but that's still about 1,000 to 1,500 specialists too many." "The article also states 'To win in your market, you'll have to prove that your group practice or IPA is cost-effective and quality-conscious."

\*Effective March 1, 1995 United Health Care is only reimbursing at Zoladex's AWP. We expect other health plans including Community Mutual and Choice Care to follow suit.

\*United Health Care current plans are to enter into the Cincinnati market and Medicare by January 1996.



Legal Division

Mark J. Haberberger Abbott Laboratories Dept 322, Bkdg. AP6D 100 Abbott Park Road Abbott Park, Illinois 60064-3500

Telephone: (708) 937-1788 Facsimile: (708) 938-1206

### By Facsimile

October 27, 1995

William C. Lucas, Esq. Zeneca Pharmaceuticals 1800 Concord Pike Wilmington, DE 19897

RE: Zeneca Marketing Activities

Dear Mr. Lucas:

We have received your letter of October 13, 1995 and are in the process of investigating the new matters raised therein as well as the adequacy of your responses to our allegations. We will respond to your letter in writing shortly.

In future correspondence, please note the correct spelling of my name.

Very truly yours,

Mark J. Haberberger

Counsel

cc: Yasu Hasegawa (all by fax)

Dean Sundberg Jim Salanty





1800 Concord Pike Wilmington Delaware 19897 USA

Bernard Turbow, M.D. 11100 Warner Avenue Fountain Valley, CA 92708

July 18, 1995

Karyn Manchester Zeneca Pharmacouticals Specialty Representative

Dear Dr. Turbow,

I realize TAP Pharmaceuticals has offered Personal Care IPA a proposal to compete with the price savings realized by using Zoladex versus Lupron. I am responding to ensure you have considered the possible consequences of this offer. I understand your comfort and proven track record with Lupron Depot. However, Zoladex is clinically equal and provides a guaranteed savings to you and Personal Care, in writing.

By purchasing Impron at it's normal price and agreeing to accept a much lower reimbursement by the IPA, you will put yourself at considerable risk. This is the TAP Pharmaceutical proposal. I realize that the TAP Representative has offered "programs" to "adjust" your statement protecting you from any type of loss, but this seems very vague. You should consider several aspects of this statement.

- Are these \*programs\* clearly defined, in writing, and approved by the TAP Pharmaceutical Headquarters?
- 2. Are these "programs" guaranteed? What if the Representative is promoted or leaves the territory, will his successor continue the "programs"?
- 3. How medically athical are these "programs"? Could they compromise you legally?

As we have discussed, the Zoladex proposal is clearly defined, in writing, and offered to every customer we do business with. Both you and Personal Care know ahead of time exactly how much you will be charged and how much you will be reimbursed. There is no unknown.

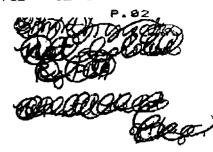
I understand there is always concern when switching drugs, however, Zoladex has proven efficacy, patient satisfaction, and cost savings unmatched by our competition. I would be happy to supply you with a list of references. Zeneca Pharmaceuticals is dedicated to Prostate Cancer. Soon we will be launching our third drug for this deadly disease. We have numerous programs to support both you and your patients through education.

The Zoladex Proposal is guranteed to save both you and Personal Care. Please feel free to contact me with any questions or concerns at 1-800-822-9209 x9522. Thank you for your consideration.

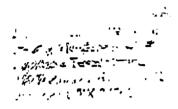
Rayn Manchester

TAP 2070238

9428086



August 28, 1995



#### Dear Doctors:

I appreciate your consideration of this financial analysis. I realize that profit is not always the main factor in shoosing a T.HRH agonist for prostate cancer. I only want to emphasize ZENECA's commitment to offering pharmacoeconomic solutions, in a time when profit margins are shrinking due to managed care and capitation.

Some key points to consider:

\* You can begin to realize the deepest discount at 72 depots versus Lupron at 101.

- \* Zolodex lessens the burden of realizing a profit from the patients and shifts it to Medicare at less cost to Medicare.
- \* With Zolodex your return on investment is substantially greater than with Lupron.
- \* With managed care and capitation coming Zolodex can be used with less of an aquisition cost and greater profit for the 72+ depot practices. This positioning will better help to market your practice to manage care and save your patients money.

In addition to these points, by using Zolodex as your preferred LHRH agonist you will also have lower overhead, less profit at risk, less out-of-pocket expenditures from the patients, and the convenience of paying with a credit card.

I want to emphasize how important your business is to me. I am dedicated to servicing this practice to the best of my ability. My focus is not only to the success of the practice, but also the patients are the key to my success as a representative. Therefore, I have offered a Zolodex New Patient Kit which will include videos, literature, and the first injection provided free of charge.

Thank you for your consideration. I believe this particular solution will work with your support of Zolodex as your preferred LHRH agonist.

Sincerely.

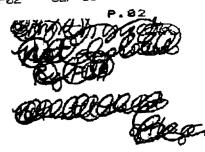
Lisa LaPoint

Zeneoa Pharmaceuticals

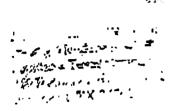
TAP 2070239

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August 28, 1995



Dear Doctors:

I appreciate your consideration of this financial analysis. I realize that profit is not always the main factor in shooting a I HRH aganist for prostate cancer. I only want to emphasize ZENECA's commitment to offering pharmacoeconomic solutions, in a time when profit margins are shrinking due to managed care and capitation.

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Thank you for your consideration. I believe this particular solution will work with your support of Zolodex as your preferred LHRH agonist.

Sincerely.

Lisa LaPoint

Zeneca Pharmaceuticals

TAP 2070240

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